



Drontal Plus

Generic Name: praziquantel/pyrantel pamoate/febantel chewable tablets

Dosage Form: FOR ANIMAL USE ONLY

Drontal Plus

(praziquantel/pyrantel pamoate/febantel)

Taste Tabs®

Broad Spectrum Chewable Anthelmintic Tablets for Dogs

CAUTION: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION:

Drontal® Plus Taste Tabs® (praziquantel/pyrantel pamoate/febantel) Broad Spectrum Chewable Anthelmintic Tablets for Dogs are available in three tablet sizes. Each size is scored for convenient oral administration.

Each Drontal Plus Taste Tabs Tablet for Puppies and Small Dogs contains 22.7 mg praziquantel, 22.7 mg pyrantel base as pyrantel pamoate and 113.4 mg febantel.

Each Drontal Plus Taste Tabs Tablet for Medium Sized Dogs contains 68.0 mg praziquantel, 68.0 mg pyrantel base as pyrantel pamoate and 340.2 mg febantel.

Each Drontal Plus Taste Tabs Tablet for Large Dogs contains 136.0 mg praziquantel, 136.0 mg pyrantel base as pyrantel pamoate, and 680.4 mg febantel.

ACTION:

Drontal® Plus Taste Tabs® Tablets contain three active ingredients having different modes of action and spectra of activity. Praziquantel is active against cestodes (tapeworms). Praziquantel is absorbed, metabolized in the liver and excreted in the bile. Upon entering the digestive tract from the bile, cestocidal activity is exhibited.¹ Following exposure to praziquantel, the tapeworm loses its ability to resist digestion by the mammalian host. Because of this, whole tapeworms, including the scolices, are very rarely passed after administration of praziquantel. In many instances only disintegrated and partially digested pieces of tapeworms will be seen in the stool. The majority of tapeworms are digested and are not found in the feces.

Pyrantel pamoate is active against hookworms and ascarids. Pyrantel pamoate acts on the cholinergic receptors of the nematode resulting in spastic paralysis. Peristaltic action of the intestinal tract then eliminates the parasite.²

Febantel is active against nematode parasites including whipworms. Febantel is rapidly absorbed and metabolized in the animal. Available information suggests that the parasite's energy metabolism is blocked, leading to energy exchange breakdown and inhibited glucose uptake.

Laboratory efficacy and clinical studies conducted with Drontal Plus Anthelmintic Tablets demonstrate that each of the three active ingredients act independently without interference. The combined tablet formulation provides a wide spectrum of activity against the indicated species of intestinal helminths.

INDICATIONS:

Drontal® Plus (praziquantel/pyrantel pamoate/febantel) Taste Tabs® Broad Spectrum Chewable Anthelmintic Tablets are indicated for removal of Tapeworms (*Dipylidium caninum*, *Taenia pisiformis*, *Echinococcus granulosus*, and removal and control of *Echinococcus multilocularis*) and for removal of Hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*), Ascarids (*Toxocara canis*, *Toxascaris leonina*), and Whipworms (*Trichuris vulpis*) in dogs.

CONTRAINDICATIONS:

DO NOT USE IN PREGNANT ANIMALS. Dogs treated with elevated levels (6 consecutive days with 3 times the labeled dosage rate) of the combination of febantel and praziquantel in early pregnancy demonstrated an increased incidence of abortion and fetal abnormalities.⁸ The effects of Drontal® Plus Anthelmintic Tablets on pregnant animals have not been determined.

There are no known contraindications against the use of praziquantel or pyrantel pamoate in dogs.

WARNINGS:

KEEP OUT OF REACH OF CHILDREN.

PRECAUTIONS:

Strict hygienic precautions should be taken when handling dogs or feces suspected of harboring *E. multilocularis*. Infected dogs treated for the first time with Drontal® Plus Taste Tabs® Tablets and dogs treated at intervals greater than 28 days may shed eggs in the feces after treatment. The animal should be held in the clinic during this interval and all feces should be incinerated or autoclaved. If these procedures are not possible, the eggs can be destroyed by soaking the feces in a sodium hypochlorite (bleach) solution of 3.75% or greater.⁷ All areas where the animal was maintained or in contact with should be thoroughly cleaned with sodium hypochlorite and allowed to dry completely before reuse.

USE DIRECTIONS

DOSAGE: The presence of parasites should be confirmed by laboratory fecal examination. Weigh the animal before treatment. Administer the proper dosage as specified in the following table as a single oral treatment.

DRONTAL® PLUS TASTE TABS® TABLETS DOSAGE CHARTS

*
NOT FOR USE IN PUPPIES LESS THAN 3 WEEKS OF AGE OR DOGS WEIGHING LESS THAN 2 LBS.

| for Puppies and Small Dogs* (2 - 25 lbs.) | | for Medium Sized Dogs (26 - 60 lbs.) | | for Large Dogs (45 lbs. and greater) | |
|---|-----------------------|--|-----------------------|--|-----------------------|
| Body Wt. (lbs.) | No. of Tablets | Body Wt. (lbs.) | No. of Tablets | Body Wt. (lbs.) | No. of Tablets |
| 2 – 4 | 0.5 | 26 – 30 | 1.0 | 45 – 60 | 1.0 |
| 5 – 7 | 1.0 | 31 – 44 | 1.5 | 61 – 90 | 1.5 |
| 8 – 12 | 1.5 | 45 – 60 | 2.0 | 91 – 120 | 2.0 |
| 13 – 18 | 2.0 | | | | |
| 19 – 25 | 2.5 | | | | |

ADMINISTRATION:

Most dogs find Drontal® Plus Taste Tabs® Tablets palatable. The tablets may be offered to the dog by hand. Alternatively tablets may be given directly by mouth or offered in a small amount of food. Fasting is neither necessary nor recommended prior to or after treatment.

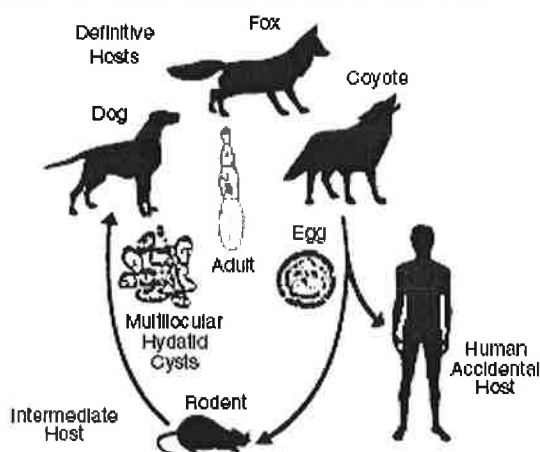
RETREATMENT:

For those animals living where reinfections are likely to occur, clients should be instructed in the steps to optimize prevention; otherwise, retreatment may be necessary. This is true in cases of *Dipylidium caninum* where reinfection is almost certain to occur if fleas are not removed from the animal and its environment. In addition, for control of *Echinococcus multilocularis*, a program of regular treatment every 21 to 26 days may be indicated (see *E. multilocularis* section below).

ECHINOCOCCUS MULTILOCULARIS:

Echinococcus multilocularis is a tapeworm species usually found in wild canids, including foxes, coyotes and wolves. The parasite has also been identified in domestic dogs and cats and is potentially a serious public health concern because it may infect humans.

The life cycle of the parasite is based on a predator-prey relationship as depicted.



The adult tapeworm is small (1-4mm) and resides in the intestinal tract of the definitive host (wild or domestic canids). Eggs from the adult tapeworm are shed in the feces. Rodents such as mice and voles serve as the intermediate host. Eggs ingested by rodents develop in the liver, lungs and other organs to form multilocular cysts. The life cycle is completed after a canid consumes a rodent infected with cysts. Larvae within the cyst develop into adult tapeworms in the intestinal tract of the canid. Eggs may be passed in the feces of the canid approximately 28 days later.

This parasite poses a serious public health problem because of the possibility for human involvement in the life cycle. If eggs shed by an infected canid are accidentally ingested, a highly pathogenic condition (Alveolar Hydatid Disease) results from development of the cyst stage in humans.

The original geographic distribution of *E. multilocularis* was primarily confined to northern areas of North America. Current evidence indicates migration of the parasite well into the continental United States.^{3,4}

Domestic dogs living in *E. multilocularis* endemic areas that roam freely with the opportunity to catch wild rodents are at risk of infection. Pet owners should be advised on how to minimize this risk. Proper restraint of dogs should be encouraged, along with regular treatment with Drontal® Plus Taste Tabs® Tablets, following the dosing schedule aforementioned and precautions indicated below.

Additional information on the life cycle and epidemiology of this parasite is available in veterinary parasitology texts.^{5,6}

DIAGNOSIS:

Diagnosis of *E. multilocularis* in canids is difficult. The adult tapeworm produces no clinical signs of infection. Tapeworm segments (proglottids) are usually not observed in the feces. *E. multilocularis* eggs, observed using microscopic fecal examination procedures, are similar in appearance to those of common species such as *Taenia pisiformis*. Assistance in the diagnosis of *E. multilocularis* may be available from a state veterinary diagnostic laboratory. Additional information regarding areas where *E. multilocularis* is suspected or has been confirmed may be obtained from area veterinary schools or the Centers for Disease Control in Atlanta, GA.

TREATMENT:

Dogs infected with *E. multilocularis* should be treated to prevent exposure of humans to infective eggs and to break the parasite's life cycle.

The dosage of Drontal® Plus Taste Tabs® Tablets for removal of *E. multilocularis* is the same as that indicated for the removal of the other tapeworm species listed on the label. Laboratory efficacy studies conducted with Drontal Plus tablets have demonstrated the recommended dosage is 100% effective.

Under condition of continual exposure to wild rodents, retreatment of the dog at 21-26 day intervals is recommended to prevent the shedding of infectious eggs.

EFFICACY:

A total of 176 dogs and puppies with naturally acquired or experimental parasite infections were included in 4 well-controlled laboratory studies to establish the efficacy of Drontal® Plus Anthelmintic Tablets. In addition, 103 dogs and puppies were included in clinical field studies conducted in 5 veterinary clinics at different geographic locations throughout the United States to further evaluate safety and efficacy. These studies included dogs of various sizes, ages and breeds. Data from these studies demonstrated Drontal Plus Anthelmintic Tablets are safe and efficacious for the removal of the parasite species indicated on the label when used as directed. Results obtained in the laboratory and clinical studies indicate small numbers of hookworm or roundworm eggs may be passed in the feces for up to 7 days after treatment although the worms themselves were eliminated. A follow-up fecal examination should be conducted 2 to 4 weeks after treatment to determine the need for retreatment.

Palatability:

Palatability studies with Drontal® Plus Taste Tabs® Tablets were conducted at 3 different veterinary clinics in the United States. These studies included a total of 151 dogs (65 males / 86 females) representing 34 different breeds with body weights ranging from 3.8 – 190 lbs. The tablets were offered free-choice to the dogs by their owners and over 89% of the dogs willingly consumed the tablets.

ADVERSE REACTIONS:

None of the 103 dogs treated with Drontal® Plus Anthelmintic Tablets in the clinical field studies exhibited drug-related side effects. Of the 40 dogs treated with Drontal Plus Taste Tabs® Tablets in laboratory studies, two dogs exhibited vomiting, one puppy exhibited bloody/mucoid stool and one puppy exhibited watery/profuse stool.

For customer service or to obtain product information, including Material Safety Data Sheet, call 1-800-633-3796. For medical emergencies or to report adverse reactions, call 1-800-422-9874.

ANIMAL SAFETY:

Controlled safety evaluations have been conducted in dogs with Drontal® Plus (praziquantel/pyrantel pamoate/febantel) Anthelmintic Tablets. Dogs receiving up to 5 times the label dosage (35 mg praziquantel, 35 mg pyrantel pamoate and 179 mg febantel per kg of body weight) for 3 consecutive days (3 times the label duration) showed clinical signs of vomiting and non-formed stools. One dog receiving a 3 times labeled dose had elevated SGPT, SGOT, CPK and GGT readings (outside of normal range) at 6 days post-treatment. No additional findings were noted in hematology/clinical chemistry parameters nor were there any treatment-related histological lesions. Vomiting was the only side effect observed when dogs received a single treatment of 61 mg praziquantel, 61 mg pyrantel pamoate and 305 mg febantel/kg with one dog having an elevated SGPT reading (outside of normal range) at 24 hours post-treatment which had returned to normal by 7 days.

STORAGE CONDITIONS:

Drontal® Plus Taste Tabs® Tablets should be stored at or below 77 °F (25 °C).

Un-blistered whole or partial tablets should be stored in a tightly sealed container.

How is Drontal Plus Supplied

Drontal® Plus Taste Tabs® Tablets are available in three tablet sizes:

Code 08758428: 40 tabs/box for Puppies and Small Dogs

Code 08892051: 40 tabs/box for Medium Sized Dogs

Code 08892078: 30 tabs /box for Large Dogs

REFERENCES:

- ¹ Andrews P. 1976. Pharmacokinetic Studies with DRONCIT® in Animals Using a Biological Assay. *Veterinary Medical Review*. 2:154-165.
- ² Campbell WC. 1986. The Chemotherapy of Parasitic Infections. *J. Parasit.* 72(1):45-61.
- ³ Hildreth MB Johnson MD and Kazacos KR. 1991. A Zoonosis of Increasing Concern in the United States. *Compendium for Cont. Ed.* 13(5): 727-740.
- ⁴ PD Carney WP and Woods CE. 1970. Studies on Sylvatic Echinococcosis, III. Host Occurrence and Geographic Distribution of *Echinococcus multilocularis* in the North Central United States. *J. Parasit.* 56(6): 1141-1150.
- ⁵ Georgi JR and Georgi ME. 1990. *Parasitology for Veterinarians*. W.B. Saunders Co. 118-138.
- ⁶ Soulsby E.J.L. 1982. *Helminths, Arthropods and Protozoa of Domesticated Animals*. 7th Edition. Lea & Febiger. 118-138.
- ⁷ Craig PS and McPharson CNL. 1988. Sodium Hypochlorite as an Ovicide for *Echinococcus*. *Ann Trop Med. and Parasit.* 82(2): 211-213.
- ⁸ Freedom of Information Summary (FOI) NADA 133-953 Vercom Paste (febantel and praziquantel).

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